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EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,970	JAO ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1-24-04, 3-31-05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 02-24-2004, 03-31-2005 is acknowledged. Claims 1-53 are pending in this action. Claims 1-53 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 11/024329. Although the conflicting claims are not identical, they are not patentably distinct from each other because application '329 claims a dosage form comprising topiramate, a surfactant, and hydrophilic polymers. The claims recite the same polymers and surfactants as the instant application, in the same range or percentages. The only difference between '329 and the instant application is that '329 recites the limitation that the active ingredient is in granule form. However it would be

obvious to one of ordinary skill in the art to form granules for the dosage form of the instant application because granules are more easily able to be formed into compressed tablets or incorporated into capsule dosage forms.

Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/024330. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '330 recite the same dosage form as the instant claims, the same surfactants and structural polymers, and the overlapping ratios or percentages of the ingredients as in the instant claims. The only difference is the claims of application '330 recite a pharmaceutical agent of low solubility, while the instant claims recite a particular low solubility drug, topiramate. It would be obvious to one of ordinary skill in the art to substitute topiramate into the composition because topiramate is a low solubility pharmaceutical agent.

Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27, 32-39 of copending Application No. 11/024378. Although the conflicting claims are not identical, they are not patentably distinct from each other because application '378 discloses a controlled release dosage form with the same composition and active ingredients as the instant claims. The only difference is that the amounts of active ingredient are presented as both milligram amounts and percentages of the total weight of the composition in the instant application, while it is only presented in percentages in '378. It would be obvious

to one of ordinary skill in the art to adapt the percentages into milligram amounts and vice versa, to arrive at the composition of the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what solubilizing surfactants that Applicants wish to exclude from the composition, since polyvinylpyrrolidone is itself a solubilizing surfactant as Applicants themselves disclose on page 25 of the specification. It is suggested that Applicants amend limitation iii to say "no other solubilizing surfactant" in order to more clearly define Applicant's invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2-5, 7, 8, 11, 12, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/44581.

WO '581 discloses a pharmaceutical composition comprising topiramate and and polyvinyl pyrrolidone (page 17). The dosage form of the composition comprises a core of particles containing the active agent. The particles are coated with a composition with cellulose acetate and povidone (polyvinyl pyrrolidone) (pages 4-5). The composition comprises 18-21% topiramate, 8-11% povidone, 58-61% sugar spheres and a coating made of 6-9% cellulose acetate and 2-5% povidone (see page 5, lines 1-6). The particles of the core beads are 0.100 mm-2.5 mm. The lower limit of the core particle ranges is 100 microns (claim 5). The core particles contain the topiramate and povidone, therefore the topiramate and surfactant are micronized in the composition.

Table 2 on page 14 discloses compositions where the unit dosage is 50 mg and 25 mg of topiramate. The povidone is 25 mg, 12.5 or 7.5 mg. Povidone is both a solubilizing surfactant and a structural polymer.

Claims 2, 6-9, 11, 12, 14-21 rejected under 35 U.S.C. 102(e) as being anticipated by Louie-Helm et al. US 2003/0091630.

Louie-Helm discloses a dosage form comprising topiramate, in the form of compressed tablets that contain an erodible, swellable matrix along with the active ingredient [0147]. The matrix particles contain 20 wt % Polyox N-60K and 58.07 wt % Polyox N-80, and 0.5% magnesium stearate [0148]. The swellable erodible matrix is an osmopolymer. Paragraph 0129 discloses binders used in tablet formulations such as polyvinyl pyrrolidone and hydroxypropylmethylcellulose (page 13). The composition comprises between 10-80% drug [0125]. Polyethylene oxide and polyethylene glycol are synonymous. The reference teaches a composition with two polyethylene oxide polymers of differing molecular weights, with the Polyox-80 having a molecular weight of 200,000 as is claimed in claim 9. Thus Polyox-80 satisfies the structural polymer limitation. Polyethylene oxide is also a surfactant. Thus the teaching of the use of Polyox-80 satisfies the limitation of the solubilizing surfactant as well. The reference further teaches the use of another Polyox polymer of a different molecular weight that could also be a solubilizing surfactant. A preferred embodiment of the invention is for the dosage form to be administered once every 24 hours or more [0026].

Claims 2-5, 14-19, 22, 25, 26, 28, 29, rejected under 35 U.S.C. 102(e) as being anticipated by Almarsson et al. US 6699840 B2.

Almarsson discloses oral dosage forms of topiramate with excipients, such as polyvinyl pyrrolidone and hydroxypropyl methylcellulose (col. 18, lines 13-15, 47, 56-57). The reference also teaches using lubricants like polyethylene glycol (col. 19, line 41). The reference teaches the amount of topiramate in the composition can range from 10 mg-1000 mg (col. 17, lines 60-63). The reference further teaches topiramate in controlled release dosage forms and methods for treatment of seizures, epilepsy, tremors, and obesity among others (col. 1, lines 15-18). Such dosage forms are formulated using hydroxypropylmethyl cellulose, and osmotic systems, such as OROS® (Alza Corporation) (col. 21, lines 25-35). The reference further discloses a specific dosage form of their invention to comprise "a wall defining cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry of substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located with tin the cavity, wherein the drug layer comprises a salt of the topiramate" (col. 22, lines 29-44). Claim 25 recites a method for delivering high doses of topiramate by administering the composition for claim 22. Since the composition of claim 22 is anticipated by this reference, the method is also anticipated by this reference since the method step of administering the composition is a necessary step in the method of treating seizures, epilepsy, and tremors as is disclosed in the

reference. The limitation "for delivering high doses" is an intended use and does not hold patentable weight since the claim is dependent on a composition claim that does not recite any amounts of topiramate, high or low. The method of enhancing bioavailability by administering the topiramate composition of claim 22 would be an inherent property of the composition when it is administered to a patient in need thereof. In order to treat seizures, epilepsy or tremors the composition would need to be administered to a person suffering from said diseases. Thus upon administration for the treatment of these ailments the bioavailability would also be increased.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 11-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Louie-Helm et al. US 2003/0091630.

Louie-Helm discloses a dosage form comprising topiramate, in the form of compressed tablets that contain an erodible, swellable matrix along with the active ingredient [0147]. The matrix particles contain 20 wt % Polyox N-60K and 58.07 wt % Polyox N-80, and 0.5% magnesium stearate [0148]. The swellable erodible matrix is an osmopolymer. Paragraph 0129 discloses binders used in tablet formulations such as polyvinyl pyrrolidone and hydroxypropylmethylcellulose (page 13). The composition comprises between 10-80% drug [0125]. Polyethylene oxide and polyethylene glycol are synonymous. The reference teaches a composition with two polyethylene oxide polymers of differing molecular weights, with the Polyox-80 having a molecular weight of 200,000 as is claimed in claim 9. Thus Polyox-80 satisfies the structural polymer limitation. Polyethylene oxide is also a surfactant. Thus the teaching of the use of Polyox-80 satisfies the limitation of the solubilizing surfactant as well. The reference further teaches the use of another Polyox polymer of a different molecular weight that could also be a solubilizing surfactant. A preferred embodiment of the invention is for the dosage form to be administered once every 24 hours or more [0026].

Although the reference does not disclose the specific amounts as claimed by applicant in the specific ratios as claimed, one of ordinary skill in the art would be able to determine through routine experimentation the exact percentages and ratios of each ingredient to use in the composition.

Claims 1-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Louie-Helm et al. US 2003/0091630 in view of Berner et al. US 6488962.

Louie-Helm et al. has been discussed above.

The reference does not teach the use of the specific solubilizing surfactants as claimed by applicant.

Berner et al. discloses that it is well known in the art to use compositions such as poloxamers in controlled release compositions (col. 5, lines 5-10).

It would have been obvious to one of ordinary skill in the art that there are a variety of other compositions that are suitable for use as a solubilizing surfactant, and one of ordinary skill in the art would have been motivated to use poloxamers as the solubilizing surfactant because of its dual utility as both a solubilizing surfactant and as a structural polymer. The addition of a second compound that not only solubilizes the poorly water soluble active agent, but also adds structure to the composition would be beneficial maintaining the structural integrity of the composition and in controlling the release of the active agent over a prolonged period of time.

Claims 1-9, 11-53, rejected under 35 U.S.C. 103(a) as being unpatentable over Almarsson et al. US 6699840 B2.

Almarsson discloses oral dosage forms of topiramate with excipients, such as polyvinyl pyrrolidone and hydroxypropyl methylcellulose (col. 18, lines 13-15, 47, 56-57). The reference also teaches using lubricants like polyethylene glycol (col. 19, line 41). The reference further teaches topiramate in controlled release dosage forms and methods for treatment of seizures, epilepsy, tremors, and obesity among others (col. 1, lines 15-18). Such dosage forms are formulated using hydroxypropylmethyl cellulose, and osmotic systems, such as OROS® (Alza Corporation) (col. 21, lines 25-35). The reference teaches the amount of topiramate in the composition can range from 10 mg-

1000 mg (col. 17, lines 60-63). The reference further discloses a specific dosage form of their invention to comprise "a wall defining cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry of substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located with tin the cavity, wherein the drug layer comprises a salt of the topiramate" (col. 22, lines 29-44). Claim 25 recites a method for delivering high doses of topiramate by administering the composition for claim 22. Since the composition of claim 22 is anticipated by this reference, the method is also anticipated by this reference since the method step of administering the composition is a necessary step in the method of treating seizures, epilepsy, and tremors as is disclosed in the reference. The limitation "for delivering high doses" is an intended use and does not hold patentable weight since the claim is dependent on a composition claim that does not recite any amounts of topiramate, high or low. The method of enhancing bioavailability by administering the topiramate composition of claim 22 would be an inherent property of the composition when it is administered to a patient in need thereof. In order to treat seizures, epilepsy or tremors the composition would need to be administered to a person suffering from said diseases. Thus upon administration for the treatment of these ailments the bioavailability would also be increased.

Although the reference does not specifically disclose the particular percentages of each ingredient in the composition, one of ordinary skill in the art would be able to determine through routine experimentation the amounts of each ingredient to add in the composition. One of ordinary skill in the art would have been motivated to increase the amount of the active agent in the composition because the composition is intended for one-a-day controlled release of the active agent. Therefore it would have been obvious to one of ordinary skill that the amount of the active agent in such a composition would need to be greater than the amount in a dosage form that is intended for multiple administrations within a 24 hour period. Once the amount of the active ingredient is determined based on the amount necessary to treat the medical condition being treated, and based on the average patients gender, age, and weight, then the amount of the structural polymer and the solubilizing surfactant can be adjusted to optimize the formulation. The release rate is another property that can be modified based on the amount of the structural polymer and the solubilizing agents added. Thus any release profile desired can be achieved via routine experimentation to select the optimum levels of each ingredient. The generic invention is embodied and described by Almarrason.

Claims 1, 31, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable Bhatt et al. US 6368626.

Bhatt teaches the same surfactants and structural polymers as claimed by Applicant (col 12, lines 46-67, col. 13, lines 1-15). The reference also discloses a push layer comprising osmopolymers (col. 14, lines 5-25). The reference teaches a drug loading between 20-90% by weight (col. 6, line 57). The reference discloses the use of

a structural polymer between 1-90% of the composition, specifically 20.3% Polyox N-80 (see example 1, line 26). The drug layer of the prior art is the center of core of the dosage form, see Figure 1 A. Example 3 discloses 20.24% Polyox-80, 3% polyoxyl 40 stearate, 2% PVP, and 63.67% polyethylene oxide in the push layer (col. 22, lines 25-35). The reference teaches a core comprising a drug composition and a push layer comprising an osmopolymer. The dosage from also possesses a semipermeable wall and an exit orifice. The comprising language of the instant claims does not exclude the flow promoting interior wall also present in the dosage form of the prior art. The reference discloses in Example I the composition contains approx. 30% surfactant and 69% the active agent. This is a ratio of approx. 1:2. One of ordinary skill in the art would be able to determine through routine experimentation the reasonable amount of surfactant to add to maintain the desired ratio and achieve the desired release profile.

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almarsson et al US 6699840 in view of Bhatt et al. US 6368626.

Almarsson discloses oral dosage forms of topiramate with excipients, such as polyvinyl pyrrolidone and hydroxypropyl methylcellulose (col. 18, lines 13-15, 47, 56-57). The reference also teaches using lubricants like polyethylene glycol (col. 19, line 41). The reference further teaches topiramate in controlled release dosage forms. Such dosage forms are formulated using hydroxypropylmethyl cellulose, and osmotic systems, such as OROS® (Alza Corporation) (col. 21, lines 25-35). The reference teaches the amount of topiramate in the composition can range from 10 mg-1000 mg

(col. 17, lines 60-63). The reference further discloses a specific dosage form of their invention to comprise "a wall defining cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry of substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located with tin the cavity, wherein the drug layer comprises a salt of the topiramate" (col. 22, lines 29-44). The reference also incorporates by reference US 6368626 (Bhatt), which teaches the specific dosage form, which Almarsson suggested to be adapted for use with topiramate.

Bhatt teaches the same surfactants and structural polymers as claimed by Applicant (col 12, lines 46-67, col. 13, lines 1-15). The reference also discloses a push layer comprising osmopolymers (col. 14, lines 5-25). The reference teaches a drug loading between 20-90% by weight (col. 6, line 57). The reference discloses the use of a structural polymer between 1-90% of the composition, specifically 20.3% Polyox N-80 (see example 1, line 26). The drug layer of the prior art is the center of core of the dosage form, see Figure 1 A. Example 3 discloses 20.24% Polyox-80, 3% polyoxyl 40 stearate, 2% PVP, and 63.67% polyethylene oxide in the push layer (col. 22, lines 25-35). The reference teaches a core comprising a drug composition and a push layer comprising an osmopolymer. The dosage from also possesses a semipermeable wall

and an exit orifice. The comprising language of the instant claims does not exclude the flow promoting interior wall also present in the dosage form of the prior art. The reference discloses in Example I the composition contains approx. 30% surfactant and 69% the active agent. This is a ratio of approx. 1:2. One of ordinary skill in the art would be able to determine through routine experimentation the reasonable amount of surfactant to add to maintain the desired ratio and achieve the desired release profile.

It would be obvious to one of ordinary skill to use the dosage form disclosed by Bhatt to make a controlled release osmotic dosage form of topiramate because Almarsson suggests and teaches to do so. One of ordinary skill in the art would expect that the controlled released topiramate dosage form to have a reasonable level of success because Bhatt discloses that it is suitable for a wide array of active ingredients. One of ordinary skill in the art would be motivated to make the composition because Almarsson teaches that topiramate is useful for treating epilepsy, seizures and tremors.

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. US 6491949 in view of Almarsson et al. US 6699840.

Faour discloses an osmotic delivery device that comprises a core, the core comprises a first drug and a second drug. The first and second drug are enclosed in a semipermeable membrane (col. 1, lines 40-53). The first and second active ingredients are the same (col. 1, line 57). The first and second active agent containing devices have different rates of release (col. 1, lines 58-63). Differences in the rates of release of the same active ingredient is achieved via the type and amount of semipermeable membrane material used as well as the type and amount of other excipients, such as

structural polymers and osmoagents (col. 5, lines 18-33). The reference further discloses the use of an osmopolymer in the core of the first osmotic device and the coating of the second osmotic device (col. 5, lines 30-33). The reference discloses types of osmopolymers or swellable hydrophilic polymers (col. 6, lines 61-67 and col. 7, lines 1-22). The reference teaches discloses the delivery device comprises an exit means or passageway (col. 4, line 8). The reference discloses the use of surfactants such as poloxamers, polyvinyl pyrrolidone, etc (col. 11, lines 10-20). The reference discloses a composition that will provide a "substantially ascending" rate or release and drug plasma concentration because the reference teaches the device will deliver up to 100% of the drug over a period of 18-24 hours. As the semipermeable membrane breaks down and the drug is released the rate of release will increase and as the amount of drug released increases so will the drug plasma concentration.

Figure I discloses the composition in which the first drug layer surrounded by the semipermeable coating is contained with in the second drug layer surrounded by a second semipermeable coating, and a exit orifice is present. Instant claims do not specify how the first and second drug compositions are in communication in the core of the delivery device. The reference discloses that this type of delivery device is suitable for use with a wide variety of drugs, of those drugs, neuroleptics are listed. Topiramate is a neuroleptic drug.

One of ordinary skill would be able to determine through routine experimentation the desired percentages of first and second drug and desired ratio of surfactant to drug in the composition.

Faour teaches the structural limitations of the dosage form with the exception of the particular active ingredient.

Almarsson teaches the use of topiramate in an osmotic delivery device. (See rejection above for full discussion of Almarsson).

It would have been obvious to one of ordinary skill in the art to make an osmotic delivery device offering controlled release of an active substance such as topiramate, with a core that contains a first and second drug composition comprising the same active substance with different release profiles because Faour teaching this technology and Almarsson suggests making controlled release dosage forms comprising topiramate and further suggests using osmotic delivery devices. One of ordinary skill in the art would have been motivated to use topiramate in the dosage form because topiramate is a neuroleptic drug, and Faour teaches that neuroleptic drugs are suitable to be used in this dosage form. One of ordinary skill in the art would further be motivated to make an osmotic delivery device comprising topiramate because topiramate treats neuroleptic diseases and such a dosage form offering prolonged and controlled release of the active substance would be favorable to a patient population suffering from a neuroleptic disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600